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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/676,725	10/01/2003	Michael G. Rosenblum	CLFR:029USD1	2944
32425	7590	07/12/2005	EXAMINER	
FULBRIGHT & JAWORSKI L.L.P. 600 CONGRESS AVE. SUITE 2400 AUSTIN, TX 78701			GODDARD, LAURA B	
			ART UNIT	PAPER NUMBER
			1642	

DATE MAILED: 07/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/676,725	<b>Applicant(s)</b> ROSENBLUM, MICHAEL G.	
	<b>Examiner</b> Laura B. Goddard, Ph.D.	<b>Art Unit</b> 1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 26 August 2004.
- 2a) ☐ This action is **FINAL**.      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 5, 7-10 and 13-29 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 5, 7-10 and 13-29 are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

5.0.2

***Election/Restrictions***

Claims 5, 7-10, 13-29 are pending. Claims 1-4, 6, 11-12 are cancelled.

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 5, 7-9, 13-20, 23-24, 26-29, drawn to a method of treating breast cancer or cervical cancer comprising administering a composition comprising monoclonal antibody that binds to 15A8 tumor associated antigen, wherein the cancer bears a 15A8 tumor associated antigen, classified in class 514, subclass 2.
- II. Claims 5, 7, 10, 13-19, 21, 23-29, drawn to a method of treating cancer comprising administering a composition comprising a monoclonal antibody, wherein the cancer expresses an antigen that is recognized by monoclonal antibody ZME-018, classified in class 514, subclass 2.

The inventions are distinct, each from the other because of the following reasons:

The inventions of Groups I and II are materially distinct methods which differ at least in objectives, method steps and reagents. For example, Groups I and II are drawn to a method of treating cancer but each Group differs in the reagents and steps they use to treat cancers expressing different antigens:

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treating breast tumor or cervical carcinoma expressing 15A8 antigen by administering a monoclonal antibody that binds to 15A8 antigen (I) and treating cancer expressing an antigen recognized by monoclonal antibody ZME-018 by administering a monoclonal antibody that recognizes and binds the antigen (II). Each of the groups employs chemically distinct reagents to treat the various cancers that differ in antigen expression, sensitivity, and/or etiology. Searching all of the groups with all of the different reagents, antibodies, antigens, steps, or objectives would invoke a high burden of search.

Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group II, restriction for examination purposes as indicated is proper.

### **Species Election**

**A.** Claim 5 is generic to a plurality of disclosed patentably distinct species comprising cytokines with different structures and functions wherein the species are: **TNF** (claim 14), **interleukin** (claim 17), OR **interferon** (claim 19). Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

**A1.** Should Applicant elect TNF, Applicant is required to choose one species of TNF: **TNF-beta** (claim 15) OR **TNF-alpha** (claim 16). Applicant is required under 35

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U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

**A2.** Should Applicant elect interleukin, Applicant is required to choose one species of interleukin: **interleukin-1 OR interleukin-6** (both in claim 18). Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

**NOTE:** It is noted that claim 22 has not been included in the restriction requirement because Examiner has been unable to determine what antigen the 465.12 antibody binds to. Upon clarification, claim 22 will be rejoined to the appropriate Group.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura B. Goddard, Ph.D. whose telephone number is (571) 272-8788. The examiner can normally be reached on 8:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Laura B Goddard, Ph.D.  
Examiner  
Art Unit 1642



SUSAN UNGAR, PH.D.  
PRIMARY EXAMINER